

17. (withdrawn)
18. (original) The method of claim 14 wherein said composition includes at least one member selected from the group consisting of Rhus toxicodendron, Rhus graveoleus, Resculus hippocastanum and Prunus Cerasus.
19. (new) The method of claim 1 comprising about 0.5 to 5% by weight of naja.

Remarks

The present invention relates to the use of a combination of drugs which act synergistically to treat a disease wherein each one singularly would not accomplish the desired effect. Consequently, the Examiner's comments that none of the components of applicant's composition are known to treat fibromyalgia, diabetic neuropathy, etc is without merit. It is for this reason that there is an invention. Applicant has surprisingly discovered that a particular combination actually works.

The dictionary definition of disease is "a condition of a living animal of one of its parts that impairs normal functioning." Applicant by the novel combination has improved blood circulation and motor and sensory nerve conductive velocities. The disease in most cases is a result of trauma, illness, inflammation and the like which are mentioned in Galdes et al. Specific ailments such as fibromyalgia, diabetic neuropathy, etc result in the symptoms of pain and other sensations associated with the disease. Pain is a symptom while the restriction of blood flow is a disease which causes pain. It is submitted that the generic term "a disease in which there is a restriction of blood flow and a reduction in motor and sensory nerve conduction velocities" is generic to "fibromyalgia" and "diabetic neuropathy." These specific ailments are also found in other named diseases including toxic neuropathy, carpal tunnel, etc.

With regard to the term “naja”, this since Roman times in latin refers to cobra venom. Submitted herewith are pages 453-454 from Boericke’s Material Medicine with Repertory, which is recognized by the FDA for homeopathic medicines. Those skilled in the homeopathic art refer to “naja” even though the complete name is “Naja Tripudiano”. Moreover, it has been for years recognized by those skilled in the homeopathic and other medical arts that venom from bees, snakes, and the like at small amounts are considered to be mobilizers of white blood cell activity similar to Lachesis ninta. The Examiner should realize that most toxins from bees, snakes, etc are antigenic which elicit a response of white blood cells to combat the toxin. One skilled in the art would therefore recognize applicant’s meaning of the term “mobilizer of white blood cells.”

It is therefore submitted that the terms used by applicant are proper since they are terms found in common use in homeopathic compositions. The disease treated in claim 1 defines the generic ailment while “fibromyalgia” is a species thereof.

The term “an effective amount” has been further defined. However, the term has been used in other homeopathic patents, namely, patent no. 5162037 so that full faith and credit is requested of other Examiner’s recognition of the term.

The Rejection Under 35 U.S.C. 112, first paragraph

Reconsideration is respectfully request of the rejection of the claims under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement.

The specification sets forth examples for the preparation of homeopathic preparations which are to be administered topically. There is stated in Example 3, a lotion for use in treating a patient suffering from fibromyalgia. One skilled in the art would recognize that application of the composition disclosed in the Examples would be

administered topically to the area of injury or disease. No undue experiments are required to arrive at this conclusion. The present formulation is presently being marketed and attached is a product insert which tells the layman how to use the invention. According to the nature of the invention both the skilled artisan or the layman will know that the composition is to be applied topically. The state of the art on topical formulation for homeopathic compositions is well known and does not require any undue experimentation. The treatment is for a time depending upon the nature of disease and the patient. The use and application should be considered as one skilled in the art would apply the compositions and not in a vacuum.

The Examiner is mistaken in the belief that blood flow restriction is a result of inflammation. Commonly, blood flow restriction is due to trauma where the capillaries become constricted. The article in the Merck Manual cites trauma as a cause of fibromyalgia. Stress exacerbates the disease and is not a cause of the disease as indicated by the Examiner (see page 481, right hand column, lines 11-16). Even if the application errs in his theory, the composition set forth in the claims, because of the novel combination, results in the desired effects.

The Examiner cannot reach an allegation that the compositions will not work based on that which is known in the art. The present invention is a surprising discovery as evidenced by commercial success. The prior art did not take the approach of treating a patient with multiple drugs to cause a multiple effect that inherently treats the disease.

The article in the British Medical Journal substantiates the belief that the medical community considers that Arnica would be helpful. However, it should be apparent that the researchers would fail. Arnica was used in the test for treating carpal tunnel

syndrome with low potency tablets. Obviously, the acids in the gastrointestinal tract would degrade the Arnica. In addition, how much of the drug would reach the diseased area is a question. Applicant provides for topical administration at the site of the injury. Moreover, there are three components which work synergistically to produce the desired effect where a desired response is required. The response which is involved is to increase blood flow and to simultaneously improve motor and sensory nerve conduction velocity which according to the dictionary or literal meaning is a condition that impairs normal function. The act of treating does not mean "curing."

Applicant suggests that instead of the use of the term "disease" the term "neuropathy" could be used. In diabetic neuropathy the diabetes causes the neuropathy. Applicant is then treating the neuropathy rather than the disease. Not all diabetics have neuropathy so that it is possible to treat one condition which impairs normal functioning in diabetics.

The present invention compositions are presently being sold to treat those conditions which impair function in individuals. This impairment is found in people suffering from different forms of neuropathy which are occurring in their limbs. The product is being sold and has achieved commercial success. A copy of the product insert is attached. No undue experimentation is required since laymen are using the composition with reported results.

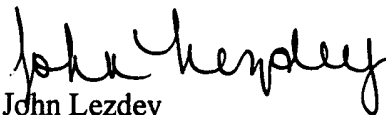
The terms used by the application and their effects are well known and documented in homeopathic literature recognized by the FDA and moreover have been recognized by the Patent and Trademark Office. The Examiner's attention is directed to patent nos. 5162037 and 4684522 which relate to homeopathic preparation and

incorporate "snake venom" and "snake's gall". These components as well as applicant's are found in Homeopathic Pharmacopedia of the United States.

In summary, applicant's components and their individual application are listed in an FDA recognized pharmacopedia. It is the unique combination which provides the relief sought in medical conditions wherein blood vessels and the motor and sensory nerves are involved. The composition has achieved commercial success with healthcare professionals. Consequently, application has demonstrated that the present claims set forth a treatment for which patent protection should be granted.

Reconsideration and favorable action in view of the foregoing are earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John Lezdey", written in a cursive style.

John Lezdey
Registration No. 22,735

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Johnson Drugs

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Waltham, MA 02452
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Lou Paradise
Topical BioMedics, Inc.
PO Box 494
Rhinebeck, NY 12572

October 29, 2002

Dear Lou,

I just wanted to drop you a note to let you know how happy I am with your products. My enthusiasm is due to the success I have had with your products. First, the products work great. Topricin is an excellent product, which works well. Second, the sales of the products are exceeding my wildest expectations.

It is rare when you come upon products where over 99% of the users are completely satisfied with the results they get. I still can't believe that after selling over 8000 pieces of Topricin, I have had a handful of people bring them back. I can't remember any other product that has had such a good success rate.

From a retailer's point of view, the product is just as great. The retail price is an easy one to sell, and with your supporting pamphlets and samples, it is almost impossible not to generate huge sales. I keep some samples in my pocket and give one out whenever I am talking to a customer. I explain to them that it is a great cream for arthritis, carpal tunnel, bursitis, muscle aches, etc., and that it is odorless, no burning, no heat, non greasy and is available in 2-oz tubes for under \$15.00. I sell it for \$13.95.

I also let the customer know that I guarantee the products 100%. I find that this usually leads to a sale and I remind the customer that I stand behind the products.

Your counter displays are fantastic. I wish I could generate the dollar sales per square foot that your counter display generates in other departments in my store. How about expanding your product line? I would love to have a Topricin section in my store.

Lastly, I want to thank you for your personnel at Topical BioMedics, Inc. It is always a pleasure to call the office and place an order or ask a question. Your support staff is very knowledgeable and extremely helpful.

I look forward to speaking with you soon.

Sincerely,

Gary L. Kracoff
Reg. Pharmacist

**LEVENSON CHIROPRACTIC CARE
355 EAST PARK AVENUE
LONG BEACH, NEW YORK 11561
TEL 516 431-1440
FAX 516 431-1969**

August 30, 2002

**Topical Bio-Medics Inc
PO Box 494
Rhinebeck, NY 12572**

Dear Christine,

I have been in practice for 34 years and tried just about every product advertised for the relief of pain (inflammation) associated with sciatica, tendonitis, carpal tunnel syndrome, sprains, strains etc. Yours is the only product we have found to be effective in 95% of the cases we have treated. Patients come back and ask "can I have more samples or what was that stuff you put on me and where can I get it?" It is by far the best product we have used.

Sincerely Yours,



Victor E. Levenson

Heather Letendre, MS, OTR/L

July 22, 2002

I am an Occupational Therapist with a Master's Degree from Boston University. Prior to be diagnosed with Multiple Sclerosis I was the Clinical Manager for Chiron Professional Services where I supervised the rehabilitation staff at three skilled nursing facilities, acted as the liaison between the therapists and the facilities' administration/nursing staff, and between the therapists and the regional director of operations. In addition, I performed all duties of a staff Occupational Therapist including direct patient evaluations, screens, and treatments.

Since being diagnosed with MS, I have found one of the most irritating symptoms to be joint pain and muscle spasms. However, I am already on several oral medications as well as a daily subcutaneous injection to "control" my MS as much as possible, so I have been hesitant to add any additional pills to what already seems overwhelming for a fairly well functioning 32 year old.

I recently saw an advertisement for Topricin CTS in my Advance Newsmagazine for Occupational Therapists and thought that this might be the answer to alleviate my chronic aches and pains. After using the samples for a few days whenever and wherever I had pain, I was so pleased that I ordered the largest quantity sold just to use on myself. I am able to sleep better now that my minor muscle spasms and the aches in my wrists, elbows, shoulders, and knees are gone. And best of all, I am not adding more pills to my daily regime. In addition, I have found that Topricin CTS has helped to reduce the itching, swelling, and pain I get from my daily injections (a typical side effect). And applying the cream is in itself therapeutic as it encourages self soft tissue massage while moisturizing the skin and virtually eliminating pain. I am also applying the cream to a scar where I had stitches done five months ago, and Topricin CTS seems to be softening the area and making the scar less noticeable.

As a therapist, I have recommended this cream to a friend with severe carpal tunnel syndrome and peripheral neuropathy. He tried the samples and said it was the first cream he had ever tried that really helped. I also have given samples to my husband and other friends for back pain, headaches, and general muscle aches and every one that has tried it says it is fantastic. This should be part of every clinic and home.

I fully recommend this product as both a therapist (MS, OTR/L) and as a patient with Multiple Sclerosis. Topricin CTS really works!

Sincerely,

Heather Letendre MS, OTR/L

Heather Letendre, MS, OTR/L



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Mr. Lou Paradise
President
Topical BioMedics Inc
Rhinebeck, NY 12572

Dear Lou,

For the last 6 years I did not find anything better dealing with pain and trauma injuries then Topricin. I constantly use it for my patients, clients and students with great success in rehabilitation, conditioning and training programs.

Many of my clients are high profile athletes who compete at the Olympic and professional levels. They include celebrities in figure skating, tennis, ballet and various sports. To be at their best they demand the best and Topricin provides this, as a reliable compliment to my therapies.

I highly recommend the use of Topricin for the serious athlete, trainer and therapist.

Sincerely,

Igor N. Burdenko, Ph.D.

Founder/President

The Burdenko Water and Sports Therapy Institute
Boston, MA

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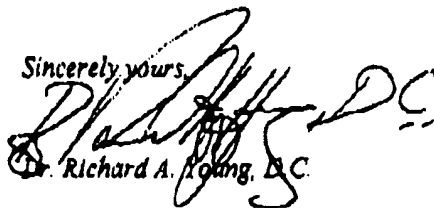
December 05, 2002

Topical BioMedics, Inc.
P.O. box 494
Rhinebeck, NY 12572

Dear Steve,

I have been practicing as a chiropractor for 10 years. During the past six years, I have successfully treated hundreds of automobile accident related soft tissue and trauma injuries using Topricin. Topricin is used in my practice as a healing treatment for sprain/strain injuries, bruises, hematomas, inflammation, minor cuts, scrapes, abrasions, dislocations, fractures, torn muscle fibers, scar tissue, heel spurs, and arthritis. Some patients have even reported using topricin successfully on fire ant and other insect bites. Topricin promotes healing and increases recovery time from soft tissue and trauma injuries. It provides immediate relief of inflammation and pain and reduces joint stiffness and swelling.

Sincerely yours,



Dr. Richard A. Young, D.C.

RAY/mjy

Heather Letendre, MS, OTR/L

July 22, 2002

I am an Occupational Therapist with a Master's Degree from Boston University. Prior to being diagnosed with Multiple Sclerosis I was the Clinical Manager for Chiron Professional Services where I supervised the rehabilitation staff at three skilled nursing facilities, acted as the liaison between the therapists and the facilities' administration/nursing staff, and between the therapists and the regional director of operations. In addition, I performed all duties of a staff Occupational Therapist including direct patient evaluations, screens, and treatments.

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I fully recommend this product as both a therapist (MS, OTR/L) and as a patient with Multiple Sclerosis. Topricin CTS really works!

Sincerely,

Heather Letendre, MS, OTR/L

Heather Letendre, MS, OTR/L



Jill Cary Levendowski
1143 Eighth Street, #2
Monterey, CA 93940

Christine Sause
Topical Biomedics, Inc
P.O. Box 494
Rhinebeck, NY 12572

Re: Your CTS lotion is an awesome product!

Dear Christine Sause:

My husband and I use and enjoy your product 365 days of the year!

Just over a year ago, my husband was suffering from chronic neck and shoulder pain. We noticed your product at our homeopathic doctor's office, Dr. Jeff Lester. Since I have been trained as a Certified Massage Therapist, we decided to give your therapeutic remedy lotion a try. I always purchase the professional size bottle because of the handy dispenser spout. The lotion has been a blessing and we're totally jazzed that the lotion is "homeopathic safe."

I have my own personal challenges as well! Eighteen years ago, I was in a car accident where I received brain injury and was in a coma for 75 days. From this happening, disability was the outcome. The right side of my body was affected, similar to as if I had a stroke. Foot drop is the result, due to a tight central muscle that runs from my toes to the top of my leg. It was many years before I had enough functionality to develop my skills as a massage therapist. When I apply Topricin CTS to my leg, it's as if I'm telling the tight muscle to relax. I have had a number of massages which also relaxes the muscle, when they work directly on it, but this is so much quicker, easier and less expensive.

Just recently, I started experiencing some severe pain in my lower right shoulder that I believe is related to my accident. I've been applying Topricin CTS on it and in no time at all it started relieving the pain. The more times that I apply it, the deeper the release gets.

Thank you very much for a healthy way to keep me getting around on my feet without pain!

Sincerely,

A handwritten signature in cursive script, appearing to read "Jill", followed by a small flourish.

Jill Cary Levendowski

NAJA TRIPUDIANS

453

NAJA TRIPUDIANS

(Virus of the Cobra)

Naja produces a typical bulbar paralysis (L. J. Boyd). Causes no hæmorrhage but only œdema, hence the victims of this reptile frequently bear very little sign of external injury, a small scratch or puncture being the only indication where the fangs have worked their havoc. The tissue lying beneath the wound is colored dark purple, and a large quantity of viscid blood-like fluid collects in the vicinity of the wound. An intense burning pain at the spot bitten is the first symptom. In man there follows an interval before fresh symptoms occur. The average is about an hour. Once developed, the symptoms follow a rapid course. A feeling of intoxication is produced, followed by a loss of power over the limbs. The patient is bereft of speech, swallowing, and the control over the movement of the lips. The saliva is ejected in large quantities, the respiration gradually becomes slower and slower, and at length ceases. Conscious all time. Is not a hæmorrhagic or septic, medicine like *Lachesis* and *Crotalus*. Its action settles around the heart; valvular troubles. Marked surging of blood upwards, marked dyspnœa, inability to lie on left side. Hypertrophy, and valvular lesions. *Organs seem to be drawn together*. Very susceptible to cold. With heart symptoms, pain in forehead and temples. Diseases primarily depending upon degeneration of motor cells. Control of sphincters lost.

Mind.—Broods constantly over imaginary troubles. Suicidal insanity. [*Aur.*] Depressed. Aversion to talking. Blurred speech. Melancholy. Dreads to be left alone. Fear of rain.

Head.—*Pain in left temple and in left orbital region, extending to occiput, with nausea and vomiting. Hay-fever, with dry larynx. Suffocative spells after sleeping. [Lach.] Eyes staring. Ptosis of both lids.*

Ears.—Illusions of hearing; otalgia; chronic otorrhœa, black discharges; smells like herring brine.

Respiratory.—Grasping at throat, with sense of choking. *Irritating, dry cough, dependent on cardiac lesions. [Spong.; Lauroc.]* Sticky mucus and saliva. Asthmatic constriction in evening. Asthma beginning with coryza.

NAJA TRIPUDIANS—NAPHTHALINE

Heart.—Dragging and anxiety in præcordia. Feeling of weight on heart. Angina pangs extending to nape of neck, left shoulder and arm with anxiety and fear of death. With the heart symptoms pain in forehead and temples. Pulse *irregular in force*. Threatened paralysis of heart, body cold, pulse slow, weak, irregular, tremulous. *Acute and chronic endocarditis*. Palpitation. Stitching pain in region of heart. *Damaged heart after infectious diseases*. Marked symptoms of low tension. [*Elaps, Vipera.*]

Female.—Neuralgia of left ovary; often serviceable in obscure pain in left groin, especially in post-operative cases; *seems to be drawn to heart*.

Sleep.—Profound, like a log, with stertorous breathing, a typical reptilian state.

Modalities.—*Worse*, from use of stimulants; *better*, from walking or riding in open air.

Relationship.—Compare: Serpent poisons generally. *Bungarus Fasciatus* (Banded Krait). This venom produces a condition like an acute polioencephalitis and myelitis, both symptomatically and histologically. *Lach.*; *Crotal.*; *Spig.*; *Spong.*

Dose.—Sixth to thirtieth potency.

NAPHTHALINE

(A chemical compound from Coal-tar; Tar Camphor)

Coryza, hay-fever, phthisis pulmonalis, also gonorrhœa have been influenced favorably by this drug. Pyelonephritis. Irritation of the periphery of the urinary apparatus. Whooping-cough.

Head.—Lying as if stupefied by a narcotic. Restless. Face pale yellowish hue.

Eyes.—Marked affinity for the eye. It produces detachment of the retina; papillo-retinal infiltration; deposits in patches upon the retina; amblyopia and consecutive amaurosis; sparkling synchysis; soft cataract. Exudation in the retina, choroid and ciliary body. Cataract. *Opacity of the cornea*.

Urine.—Irresistible desire. Meatus red, swollen, and œdema of prepuce. Black urine. Cutting pain down penis. Pain in bladder. Terribly offensive odor of decomposing ammoniacal urine.

DRAFT Pages 4

Diabetes and the complications of Diabetic Neuropathy

According to the American Podiatric Medical Association, Diabetes mellitus is a chronic disease that affects the lives of about 16 million people in the United States, 5.4 million of whom are unaware that they even have the disease. Every day 2,200 new cases of diabetes are diagnosed and an estimated 780,000 new cases are identified each year. The disease is marked by the body's inability to manufacture or properly use insulin, and impairs the body's ability to convert sugars, starches, and other foods into energy. The long-term effects of the elevated blood sugar (hyperglycemia) damage the eyes, heart, kidneys, blood vessels and peripheral and autonomic nerves.

Symptoms of hyperglycemia may include frequent urination, excessive thirst, extreme hunger, unexplained weight loss, tingling, numbness or burning in the feet or hands, blurred vision, fatigue, slow-to-heal wounds, and susceptibility to certain infections. People who have these symptoms and have not been tested for diabetes are putting themselves at considerable risk and should see a physician immediately.

Keeping blood sugar in balance is a major part of controlling the disease.

The socioeconomic costs of diabetes are enormous. The dollar costs have been estimated at \$98 billion annually, about \$44 billion of which are direct costs from the disease with \$54 billion indirectly related. Diabetes is the sixth leading cause of death in the United States, and individuals with diabetes are two to four times more likely to experience heart disease and stroke.

The growth of the disease worldwide is especially alarming. **The World Health Organization (WHO)** expects the number of new diabetes cases to double in the next 25 years from 135 million to nearly 300 million. Much of this growth will occur in developing countries where aging, unhealthy diets, obesity, and sedentary lifestyles will contribute to the onset of the disease.

- According to recent surveys, about 86,000 lower limbs are amputated annually due to complications from diabetes (uncontrolled Peripheral Neuropathy).
- Diabetes is the leading cause of end-stage kidney disease, accounting for about 40 % of new cases.
- Diabetes is the leading cause of new cases of blindness among adults, age 20 to 70

While there is currently no cure for diabetes, early diagnosis with a proper diet, exercise, medical care, and careful management at home, a person with diabetes can keep the most serious complications of the disease at bay and enjoy a long, full life.

Because diabetes is a systemic disease affecting many different parts of the body, ideal case management requires a team approach. Prevention of the escalation and complications of peripheral neuropathy is essential. A podiatric physician becomes an integral part of the treatment team, where success in the prevention of amputations is well documented, as it is one of the most serious conditions of the disease that they treat.

In addition to the annual check-ups with these professionals there are warning signs that a person with diabetes should be aware of so that they may be identified and called to the attention of the family physician or podiatrist.

These symptoms include:

- Skin color changes in the toes feet or legs
- Elevation in skin temperature
- Swelling of the foot or ankle
- Pain in the feet or legs
- Open sores on the feet that are slow to heal or do not heal
- Ingrown or fungal toenails
- Bleeding corns or calluses
- Dry cracks in the skin, especially around the heel

Controlling the diabetes is essential in the treatment of neuropathy.

According to the patient page on Peripheral Neuropathy by the Journal of the American Medical Association (JAMA) The nervous system is vast and complex network of neurons (individual nerve cells) and the nerves (bundles of nerve fibers from neurons) that provide information to the brain and communications from the brain and spinal cord (and within the brain) to make possible that normal functions of the entire body.

The nervous system consists of two distinct parts: the central nervous system (composed of the brain and spinal cord) and the peripheral nervous system (composed of a network of nerves and neurons outside the central nervous system which is connected to the spinal cord). The peripheral nervous system is composed of sensory (C-fibers) nerves that communicate sensory information to the brain, like pain for example, and the motor (A-delta fibers) nerves that send information to control the muscles.

According to the National Institute of Neurological Disorders and Stroke (NINDS) Peripheral Neuropathy is a common neurological disorder resulting from damage or impairment of cells in the peripheral nervous system. The impairment or damage can be associated with conditions and systemic diseases such as diabetes. Causes may also include mechanical pressure, penetrating injuries, contusions, fracture, dislocated bones, and the prolonged use of crutches. Also any disease or disorder that causes a lack of or insufficient blood circulation to the nerve cells, such as (atherosclerosis hardening of the blood vessels) or high blood pressure common in diabetes. These disorders prevent essential oxygen and nutrients to arrive at the nerve cells causing nerve damage and abnormal function of the nerve itself, where nutrients within the nerve are not properly metabolized. Diabetes can also affect blood vessels in the feet and cause them to narrow. This is known as diabetic vasculopathy." The narrowing blood vessels carry less blood and the foot may change colors, a cold blue, purplish or pale color is a sign of poor circulation. Diabetic neuropathy affects the nerves that supply sensation to the feet.

As a result patients have diminished feeling in their feet and need to examine their feet regularly to detect injuries and wounds they don't feel. Left unchecked open wounds could cause infections and foot ulceration that could eventually lead to gangrene. Gangrene is a serious and dangerous infection which if not treated could require an amputation of the affected foot or leg to save the rest of the lower extremity. General poor nutrition to the body (equals poor nutrition to the nerve cells) another factor causing chemical imbalances that further adversely affect nerve health and function. Other causes include disorders and diseases that affect the myelin sheath that protect certain nerves also causing nerve conduction to be impaired or cause a misfiring of nerve impulses along the nerve. Yet another factor is direct damage to the nerve cells from trauma injury, pressure and entrapment as is the case with carpal tunnel syndrome. Diabetes remains the leading cause of peripheral neuropathy.

According to JAMA the following are also causes of peripheral neuropathy:

- Not having good control of blood sugar levels when diabetes is present
- Excessive alcohol consumption
- Nutritional deficiencies or problems absorbing nutrients
- Infections
- Inflammation
- Heavy metal poisoning from lead and or mercury or from toxic chemicals such as arsenic
- Abnormal growths such as tumors, that may also cause nerve damage
- Autoimmune diseases (such as rheumatoid arthritis and lupus for example)
- Metabolic disorders such as those caused when the kidneys are not functioning properly

Symptoms of Peripheral Neuropathy:

- Insensitivity to pain or temperature
- Extreme sensitivity to touch, even light touch
- Sharp pains or cramps
- Loss of reflexes and muscle weakness
- Paresthesia (abnormal sensations such as tingling burning pricking sensations), and numbness especially in the extremities (feet and legs occasionally in the hands and arms)
- Pain especially in the legs and feet that is worse at night
- Loss of balance and coordination

Polyneuropathy "is a neuropathy pattern" where the nerve damage initially starts in both feet and may progress to involve the feet calves, and fingers and hands. Another word to describe this ailment is a "Stocking and Glove Neuropathy". Many patients with Polyneuropathy may not even have any symptom and it is necessary to conduct a physical exam and laboratory testing such as electromyography (EMG). Others describe the symptoms as follows: burning, raw skin, skin sensitivity, sharp pain, electric shock, deep ache, freezing cold, like walking on ground glass, itchy, and others. Some report not exactly pain but uncomfortable irritating sensations including vibrations, like bugs crawling etc. This is constant pain to only painful at night with pain strong enough to interfere with their sleep. Others with neuropathy report having trouble with their balance when walking. As with all chronic pain, patients with painful neuropathies develop depression and suffer the affects of sleep deprivation.

Profile for Diabetic (Peripheral Neuropathy):

Nerve inflammation (edema) restricts blood flow and causes misfiring of nerve impulses.

High blood Glucose levels damage capillaries feeding the peripheral nerves. The nerves suffer from insufficient blood flow and a deficiency of oxygen and nutrients causing damage to the nerves.

High blood glucose levels cause chemical changes that impair the nerves ability to transmit electrical nerve impulses. These chemical changes impair the nerves ability to metabolize nutrients.

Recent research suggests that excessive glucose metabolism effects the level of Nitric Oxide in the nerves. Nitric Oxide pathways dilate blood vessels. In a person with diabetes low levels of nitric oxide may lead to further constriction of blood vessels supplying the nerve and contribute to nerve damage

High glucose levels affect many metabolic pathways in the nerves leading to an accumulation of sugar known as sorbitol and depletion of a substance called myoinositol.